

37 C.F.R. § 1.8

September 23, 2008 Electronic signature: / Melissa L. Sistrunk /
Date Melissa L. Sistrunk (Reg. No. 45,579)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

For: MICROFABRICATED APPARATUS FOR
CELL BASED ASSAYS

70393398.1

REQUEST

A. PROCEDURAL HISTORY

Regarding the above-referenced patent application, Appellants initially filed their appeal brief on December 14, 2006, in response to the final Office Action dated May 17, 2006. An amended Appeal Brief in response to a Notice of Non-Compliance under 37 C.F.R. §1.192(c), dated March 29, 2007, was filed on April 26, 2007. An Examiner's Answer was mailed on August 8, 2007, and no Reply Brief was filed. A Decision on Appeal was mailed on July 23, 2008. Appellants herein submit this Request for Rehearing in accordance with 37 C.F.R. §41.52.

B. ARGUMENT

In accordance with 37 C.F.R. §41.52, Appellants submit this Request for Rehearing to request that the Board of Patent Appeals and Interferences reconsider its Decision on Appeal dated July 23, 2008, and reverse the following rejections:

- the rejection of claims 22-25 and 33-38 under 35 U.S.C. §103 as being unpatentable over Sheppard, Jr. et al. (U.S. Patent No. 6,143,247) in view of Mian et al. (U.S. 6,319,469) and Cathey et al. (U.S. 5,660,993);
- the rejection of claims 21, 26, and 29-32 under 35 U.S.C. 103 as being unpatentable over Sheppard, Jr. et al. (U.S. Patent No. 6,143,247) in view of Mian et al. (U.S. 6,319,469) and Cathey et al. (U.S. 5,660,993) and taken further in view of Chen et al. (U.S. 5,800,778);
- the rejection of claims 27 and 28 under 35 U.S.C. § 103 as being unpatentable over Sheppard, Jr. et al. (U.S. Patent No. 6,143,247) in view of Mian et al. (U.S. 6,319,469) and Cathey et al. (U.S. 5,660,993) and Chen et al. (U.S.

- 5,800,778) taken further in view of Wolfe et al. (U.S. Patent No. 5,190,879); and
- the rejection of claims 39 and 40 under under 35 U.S.C. § 103 as being unpatentable over Sheppard, Jr. et al. (U.S. Patent No. 6,143,247) in view of Mian et al. (U.S. 6,319,469) and Cathey et al. (U.S. 5,660,993) taken further in view of Cook (WO 94/26413).

1. Standard of Review

The Federal Circuit has held that findings of fact by the Board of Patent Appeals and Interferences must be supported by “substantial evidence” within the record. *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000). In *Gartside*, the Federal Circuit stated that “the ‘substantial evidence’ standard asks whether a reasonable fact finder could have arrived at the agency’s decision.” *Id.* at 1312. See also *Matsushita Elec. Indus. Co. v. United States*, 750 F.3d 927, 933 (Fed. Cir. 1984) (A decision is supported by substantial evidence when “a reasonable mind might accept [it] as adequate to support a conclusion.”). Accordingly, it necessarily follows that an Examiner’s position on appeal must be supported by “substantial evidence” within the record in order to be upheld by the Board of Patent Appeals and Interferences.

2. Cathey Fails to Teach the Valve Element

The Board, in its Decision on Appeal, affirmed each of the rejections under 35 U.S.C. §103(a). In accordance with 37 CFR § 41.52, Appellants respectfully assert that the Board has overlooked particular arguments and misapprehended a prior art reference and file this Request for Rehearing accordingly. This Request for Rehearing is predicated on the issue that one of the references, Cathey (U.S. Patent No. 5,660,993), fails to provide a claimed element in the combination of references used in the multiple rejections under 35 U.S.C. §103(a). Therefore,

Appellants will discuss this matter with the intention of application of the arguments to all pending rejections under 35 U.S.C. §103(a). In particular, Appellants assert that the Board has misapprehended the Cathey reference in addition to overlooking certain of Appellants' arguments.

The Patent Office cites Cathey as supplying the hydrophobic valve element of Appellants' claims (see at least Page 4 of the Final Office Action of May 17, 2006), but Appellants assert that the cited portion of Cathey does not supply the hydrophobic valve element. The Examiner contends that in column 5, lines 46-60, Cathey allegedly teaches the art-recognized equivalents of capillary valves and localized region of hydrophobicity. The passage is provided as follows:

Control of fluid flow through the main and side reagent channels may be enhanced through use of a variety of means. For example, where one desires to enhance fluid flow through a device, one may provide for hydrophilic regions in the channel at the appropriate region, where the hydrophilic region serves to attract and draw fluid through that region. Alternatively, ***where one wishes to slow or impede fluid flow through a particular region of the channel***, one may provide for hydrophobic areas in that particular region. Another means of enhancing control of fluid flow through the device is to employ one or a plurality of capillary valves, which may be located at various positions along the main and/or side reagent flow paths, usually being positioned at a region of the channel upstream from the incubation area. (emphasis added)

Thus, the Cathey disclosure fails to teach hydrophobic valves, as claimed in the subject invention. Cathey instead teaches slowing or impeding of fluid flow, but this does not teach a valve. The skilled artisan recognizes based on Appellants' disclosure (at least paragraphs [0036] and [0037] of US 2004/0058408) that a **valve** acts as a point to stop and resume flow, as opposed to merely hindering the flow as in Cathey. In the Decision on Appeal, the Board characterizes the above-referenced passage as Cathey teaching "localized regions of hydrophobicity to serve as valves for the control of fluids." However, Cathey does not teach that these regions serve as

valves, only regions to impede fluid flow. Based on Appellants description, the skilled artisan recognizes that the claimed valve acts as follows (see paragraph [0036]):

“...liquid flow in the micro-channel elements can be controlled by application of a defined centrifugal force to cause the liquid to flow in a channel..., wherein the same force is insufficient to cause the liquid to flow in further linked channels..., this having the effect of stopping the liquid flow at a desired position in the micro-channel element.”

Also described in paragraph [0037]:

“...application of a defined force to liquid in channel (1), sufficient to cause liquid to move down this channel will be insufficient to cause that liquid to enter the second channel (4) of higher hydrophobicity, this having the effect of stopping the liquid flow at a desired position in the micro-channel element.”

Furthermore, the term “impede” in the expression “...where one wishes to slow or impede fluid flow...” in Cathey could easily have been replaced by the term “prevent” if Cathey had indeed envisaged the use of hydrophobic areas to prevent flow, as opposed to merely slow it down or limit it. The ambiguous term “impede” should surely not be interpreted in its sense which is most harmful to the applicant without some motivation in the prior art document for it being interpreted in that way. In addition, even if Cathey had stated “prevent” that would not have meant that the hydrophobic area was a valve, as it would have been considered a static barrier. A valve is a dynamic device that can change between two or more states - in the case of a hydrophobic valve the states of permitting or preventing the passage of fluid.

Thus, Cathey fails to describe a hydrophobic valve, and Appellants respectfully assert that the Board misapprehends the disclosure of Cathey. Therefore, given that the combination of references do not teach or suggest each limitation of the claims, there can be no finding of obviousness.

Appellants further assert that the Board overlooks particular arguments set forth in the appeal. In particular, Cathey describes the use of hydrophobic areas or capillary valves, yet

Appellants argued that there is no art-recognized equivalence for hydrophobic regions and capillary valves. The capillary valves actually used by Cathy are unrelated in structure or mechanism of function to the claimed hydrophobic valves. Appellants re-assert that the Patent Office rejection represents an impermissible hindsight reconstruction of the claimed subject matter. As a result, the Patent Office erroneously reads into the prior art the hydrophobic valve element. *Graham v. John Deere*, 383 U.S. 1, 36 (1966) (Observing that one must guard against “slipping into use of hindsight” and reading the claimed subject matter into the prior art.); *In re Shuman*, 361 F.2d 1008, 1012 (CCPA 1964) (“It is impermissible to first ascertain factually what appellants did and then view the prior art in such a manner as to select from the random facts of that art only those which may be modified and then utilized to reconstruct appellants’ invention from such prior art.”). The Patent Office thus lacks substantial evidence to support the conclusion that the claimed subject matter is obvious. Because the Patent Office rejection constitutes an arbitrary and capricious decision and is lacking substantial evidence in support, the Patent Office should be reversed. 5 U.S.C. § 706(2)(A) & (E) (Administrative Procedures Act). This matter was not addressed by the Board, however.

Appellants assert that the Board also failed to recognize Appellants’ arguments that Cathey does not support the position that the skilled artisan recognized hydrophobic valves as equivalents to capillary valves. MPEP § 2144.06. The case law on this subject is consistent. Evidence of equivalency was found in the prior art in the form of reduction to practice of the two equivalents in what were the same or very similar circumstances. *In re Fout*, 675 F.2d 297, 301 (CCPA 1982); *In re Siebentritt*, 372 F.2d 566 (1967); *Smith v. Hayashi*, 209 USPQ 754, 759 (Bd. of Pat. Inter. 1980). Thus, it was reasoned, one of skill in the art, aware of the prior art, would understand from these teachings that these were substitutable equivalents in the context of

the particular environment at issue. Cathey makes no such disclosure of a reduction to practice of hydrophobic valves. Rather Cathy exclusively employs capillary valves. *e.g.* Fig. 4 and col. 12, ln 13-32. Cathy does not reference other prior art that actually uses hydrophobic valves. Cathey does not even characterize hydrophobic areas as a “typical” valve structure or otherwise indicate in general terms that hydrophobic valving was well known in the art. Applicant asserts that it cannot be *prima facie* obvious to substitute structurally and mechanistically different means for valving without some evidence of successful reduction to practice of both means in a relevant context. The Patent Office cites no such evidence and the limited statement in Cathey does not suffice as such, and the Board has failed to address this issue.

3. Conclusion

In conclusion, Appellants respectfully request that the Board reconsider affirmation of the Examiner’s rejections in light of the erroneous interpretation of Cathey and in light of the arguments not previously considered in the Decision.

C. CONCLUSION

WHEREFORE, Appellants respectfully request that the Board reverse the rejection of claims 21-40 under 35 U.S.C. §103(a).

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Respectfully submitted

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